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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/027,186  | 12/20/2001  | Francis Lee          | LD0251NP            | 9673             |
| 7590 06/01/2004   |             |                      | EXAMINER            |                  |
| BARRY J. MARENBERG, ESQ.<br>MINTZ, LEVIN, COHN, FERRIS, GLOVSKY & POPEO, P.C.<br>ONE FINANCIAL CENTER<br>BOSTON, MA 02111 |             |                      | WANG, SHENGJUN      |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1617                |                  |

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/027,186

Applicant(s)

LEE, FRANCIS

Examiner

Shengjun Wang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7, 8, 14, 15, 22-24, 37, 39 and 61-76 is/are pending in the application.
- 4a) Of the above claim(s) 62-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 8, 14, 15, 22-24, 37, 39, 61 and 76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Receipt of applicants' amendments and remarks submitted October 3, 2003 is acknowledged.

1. Newly submitted claims 62-76 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

2. Inventions of claims 62-75 and the claims 1-4, 7, 8, 14, 15, 22, 23, 37, 61, 76 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because anticancer drug may be combined with anticancer composition other than those defined in claims 1-4, 7, 8, 14, 15, 22, 23, 37. The subcombination has separate utility such as use alone as anticancer agent.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 62-76 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The claims have been examined insofar as they read on elected invention, e.g., the combination of A4-P and taxol.

### ***Claim Rejections 35 U.S.C. 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7, 8, 14, 15, 22-24, 27, 37, 39 and 61, 76 are rejected under 35 U.S.C.

103(a) as being unpatentable over the Pettit patent of record taken with the Cahan et al. reference.

The Pettit patent teaches applicants' compound (wherein 1 is h see col. 1, line 55 to col. 2, line 15) for the "treatment of one or more neoplastic diseases. For example, . . . , malignant melanoma, . . . breast carcinoma, . . . Ovarian carcinoma, . . . , and the like" (col. 6, lines 2-7) in "humans" (col. 6, line 28). The Cahan et al. reference teaches that taxol "has shown clinical activity against several tumors, including ovarian and breast carcinoma and melanoma" (AB, lines 1-3). The above reference and patent do not teach the combination together. However, one skilled in this art would find ample motivation from the prior art supra to combine the well know anticancer agents together where the results obtained thereby are no more than the additive effects of the anticancer agents; particularly since the above prior art teaches the ingredient for treating the same cancer systems. See In re Sussman, 1943 C.D. 518. The data of record is noted but the showing in Figures 8-10 shown taxol alone to be better or equal to the elected combination. Moreover, Applicants state on page 40, lines 2-9 of the specification that "results indicate that administration of the two agents simultaneously was deleterious to the overall efficacy of the combination in this model (Fig. 9). Allowing an interval of 3 hr between the administration of the two agents did not restore the overall efficacy of the combination, but overall efficacy was restored at an interval of 24 hours."

It is noted that the Pettit patent issued claim 2 is directed to treating "cells effected

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with a neoplastic disease" broadly. It is further noted that the instant elected combination is directed to well-known anticancer agents. Further, note the optimization of a result effective parameter, e.g., the schedule of administering the therapeutical agents, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

***Response to the Arguments***

Applicants' amendments and remarks submitted October 3, 2004 have been fully considered, but are not persuasive.

Applicants argue that there would have been no motivation to combine the two known anticancer agents, taxanes and CA4P as herein claimed because the two agents have different mechanisms in inhibiting cancer cells. The arguments are not persuasive. The mechanisms may be different, but the ultimate utilities are the same, i.e., treating cancer. It is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two known anticancer agents sets forth prima facie obvious subject matter.

Applicants further contend that taxanes and CA4P are known to have opposite modes of action, and therefore, it is not obvious to combine the two agents. It is well settled that a known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Further, applicants admitted on the record that the combination yields no more than what a skilled artisan expected. Applicants state on page 40,

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lines 2-9 of the specification that “results indicate that administration of the two agents simultaneously was deleterious to the overall efficacy of the combination in this model” (Fig. 9). Optimizing a schedule so that the two are not conflicted each other would be within the skill of artisan.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

  
**SHENGJUN WANG**  
**PRIMARY EXAMINER**

5/21/04